



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/330,235 06/10/99 KNUTZON

D 17256/01

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HM22/1107

[REDACTED]
EXAMINER

MCELWAIN, E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED:

11/07/01

[Signature]

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/330,235	KNUTZON, DEBBIE
	Examiner	Art Unit
	Elizabeth McElwain	1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 August 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-12 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Applicant's election with traverse of Group I, claims 1 and 4-12 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that Groups II and III are not distinct methods, and may be preferred modes of accomplishing the same invention. Claims 13-18, of Groups IV and V have been cancelled.

Upon further review of the claims, the Examiner has regrouped claims 2 and 3 with the claims of
5 Group I. Claims 1-12 are examined in this office action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

10 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

15 Claims 1-12 are drawn to a method of producing stearidonic acid in a plant seed by growing plant that has introduced into its genome a delta-6 desaturase gene and may also have introduced into its genome a delta-12 desaturase gene or a delta-15 desaturase gene. However, the specification does not teach the production of any plant that has introduced into its genome either the delta-6 desaturase or the combination with either of a delta-12 desaturase or a delta-15 desaturase gene. While the specification
20 does teach the unpredictability of producing altered levels of polyunsaturated fatty acids (PUFAs) in a plant. See page 9 of the specification where it states that the production of PUFAs depends upon the host cell, the availability of substrate and the desired end product. Furthermore, it requires production of an enzyme that will function in the environment of the cell, having the appropriate pH optimum and the necessary cofactors, for example. Therefore, the production of stearidonic acid in a plant cell by
25 introducing exogenous desaturase genes is highly unpredictable.

Given the uncertainty of producing a given PUFA in a plant cell, as stated above; and given the lack of working examples of plants producing stearidonic acid by the claimed method; and given the absence of guidance in the specification with regard to which desaturase genes will function if a given

plant species to produce stearidonic acid; and given the breadth of the claims which are drawn to the use of any delta-6 desaturase, including in combination with any delta-12 or delta-15 desaturase genes in any plant species; it would require undue experimentation by one skilled in the art to make and/or use the invention.

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No claims are allowed.

10 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (703) 308-1794. The examiner can normally be reached from 8:00 AM to 4:30 PM.

15 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Group is (703) 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

20 Elizabeth F. McElwain, Ph.D.
November 5, 2001

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800
Elizabeth F. McElwain